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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,910	08/28/2003	Roger P. Jackson	10,126	8690

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John C. McMahon
PO Box 30069
Kansas City, MO 64112

EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,910

Applicant(s)

JACKSON, ROGER P.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08/28/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 8/28/2003.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

Claims 1-21 and 23-30 are objected to because of the following informalities:

In claim 1, line 6, applicant recites "a bore", while in line 9, applicant refers to the bore as "the shank receiving bore". Please amend the claims to be more consistent to be clearer for examination purposes, e.g. change "the shank receiving bore" to --the bore--.

In claim 13, line 6, "having shank mating side" should be changed to --having a shank mating side-- to be clearer for examination purposes.

In claim 14, line 4, "has inner surface" should be changed to --has an inner surface -- to be clearer for examination purposes.

Also note:

In claim 28, the term "radiused" is being interpreted as --having a radius--.

Claims 23-30 are being interpreted as being dependent from independent claim 22, not dependent claim 21 as currently recited in the claims. It is believed that applicant inadvertently made a typographical error, writing "as set forth in claim 21" while meaning "as set forth in claim 22". If applicant could please clarify this issue in the response, and make any changes as necessary.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-9, 13-14, 16, 18, 22-23, 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Nichols (U.S. Patent No. 6,090,111).

Nichols discloses a polyaxial head bone screw assembly comprising a shank having a threaded body (ref. #24) adapted be implanted a bone, a capture end (ref. #20), and a head (ref. #16) having a channel adapted to receive a rod within the channel, the head having a bore formed therethrough. The capture end of the shank is operably received within the bore of the head. A retainer ring (ref. #42) is secured on the capture end of the shank within the head capable of retaining the capture end within the head and enabling selective angular positioning of the shank with respect the head, while in an adjustment configuration. A closure member (ref. #18) is operably received in the head in such a manner as to be adapted engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in locking configuration. The retainer ring has an outer surface, of which at least a portion is substantially spherical (the circumference of ring being the portion that is "substantially spherical"). The head has a seating surface, of which at least a portion is substantially spherical

(circumference of annular groove, ref. #54) and the seating surface is capable of enabling slidable mating engagement with the retainer outer surface, when the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The capture end the shank has a frusto-conical surface diminishing in diameter toward the shank. (see grooved surface). The retainer ring (ref. #42) has a separation capable of enabling resilient expansion and contraction of the retainer ring. The retainer ring has a substantially radial split capable of enabling resilient expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a non-slip formation (ref. #26) capable of enabling non-slip engagement with a rod. The capture end of the shank has a knurled dome (ref. #26), having a radius, capable of enabling non-slip engagement with a rod within the channel of the head. The cavity has an expansion chamber above the head spherical surface that allows expansion the ring therein as the shank is inserted into the ring.

Claims 1-2, 4-7, 10, 13, 15-16, 19, 22-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brace et al. (U.S. Patent No. 6,187,005).

Brace et al. disclose a polyaxial head bone screw assembly comprising a shank having a threaded body (ref. #18 and 98) capable of being implanted a bone, a capture end (ref. #96), and a head (ref. #92) having a channel adapted to receive a rod within the channel, the head having a bore (ref. #108) formed therethrough. The capture end of the shank is operably received within the bore of the head. A retainer ring (ref. #100) is secured on the capture end of the shank within the head capable of retaining the capture end within the head and enabling selective angular positioning of the shank with

respect the head, while in an adjustment configuration. A closure member (ref. #106) is operably received in the head in such a manner as to be adapted engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in locking configuration. The retainer ring has an outer surface, of which at least a portion is substantially spherical. The capture end the shank has a frusto-conical surface diminishing in diameter toward the shank. The retainer ring has a frusto-conical retainer bore (ref. #102) formed therethrough capable of enabling mating engagement with the capture end within the retainer bore (col. 5, lines 1-15). The ring has a separation capable of enabling resilient expansion and contraction of the retainer ring. The retainer ring has a substantially radial split capable of enabling resilient expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a tool formation to enable non-slip engagement by a tool (ref. #24). The chamber above the cavity has an expansion head spherical surface that allows expansion the ring therein as the shank is inserted into the ring.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-14, 16, 18-23, 25-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,280,442).

Barker et al. disclose a polyaxial head bone screw assembly comprising a shank having a threaded body (ref. #52/56) adapted be implanted a bone and a capture end (ref. #54); a head having a channel (FIG. 3C) adapted to receive a rod within the channel, the head having a bore formed therethrough (FIG. 3C and 3D). The capture end of the shank is operably received within the bore of the head. A retainer ring (ref. #90) is secured on the capture end of the shank within the head capable of retaining the capture end within the head and enabling selective angular positioning of the shank with respect the head, while in an adjustment configuration. A closure member (ref. #120) is operably received in the head in such a manner as to be adapted engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in locking configuration. The retainer ring has an outer surface, of which at least a portion is substantially spherical (see the circumference). The head has a seating surface, of which at least a portion is substantially spherical (see the circumference of annular groove) and that capable of enabling slidable mating engagement with the retainer outer surface, when the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The retainer ring has a frusto-conical retainer bore (see FIG. 6B) formed therethrough capable of enabling mating engagement with the capture end within the retainer bore. The ring has a separation capable of enabling resilient expansion and contraction of the retainer ring (see FIG. 6A). The retainer ring has a substantially radial split capable of enabling resilient

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expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a non-slip formation capable of enabling non-slip engagement with a rod (ref. #58). The capture end of the shank has a knurled dome capable of enabling non-slip engagement with a rod within the channel of the head (ref. #58). The capture end of the shank has a tool formation to enable non-slip engagement by a tool (ref. #60). The head has an internal guide and advancement structure formed therein (see internal threading); and the closure member has a radially outward surface with an external guide and advancement structure (see threading on closure member, ref. #120) formed thereon which is sized and shaped to rotatably mate with the internal guide and advancement structure of the head. The head has an internal thread (ref. #44) formed therein; and the closure member has a radially outward surface with an external thread formed thereon which is configured to rotatably mate with the internal thread of the head.

Claims 1-3, 6-8, 11-14, 16-17, 20-23, 25-26, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Biedermann et al. (U.S. Patent Application Publication No. 2002/0143341).

Biedermann et al. discloses a polyaxial head bone screw assembly comprising a shank having a threaded body (ref. #13) adapted be implanted a bone and a capture end (ref. #14); a head having a channel (ref. #1, 22) adapted to receive a rod within the channel, the head having a bore formed therethrough. The capture end of the shank is operably received within the bore of the head. A retainer ring (ref. #15) is secured on the capture end of the shank within the head capable of retaining the capture end within

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the head and enabling selective angular positioning of the shank with respect the head, while in an adjustment configuration. A closure member (ref. #25) is operably received the head in such a manner as to be adapted engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in locking configuration. The retainer ring has an outer surface, of which at least a portion is substantially spherical. The head has a seating surface, of which at least a portion is substantially spherical and that capable of enabling slidable mating engagement with the retainer outer surface, when the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The ring has a separation capable of enabling resilient expansion and contraction of the retainer ring. The retainer ring has a substantially radial split capable of enabling resilient expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a non-slip formation capable of enabling non-slip engagement with a rod. The head has an internal guide and advancement structure formed therein (ref. #23/24); and the closure member has a radially outward surface with an external guide and advancement structure (external threading on ref. #25) formed thereon which is sized and shaped to rotatably mate with the internal guide and advancement structure of the head. The head has an internal thread (ref. #23/24) formed therein; and the closure member has a radially outward surface with an external thread formed thereon which is configured to rotatably mate with the internal thread of the head. The cavity has a first region having a partial hemispherical surface sized and

shaped to mate with a partial hemispherical surface on the retainer ring; and the cavity has second region directly accessible from the first region and having a larger radius than the first region wherein the ring is capable of expanding as joins with the shank. The cavity has a chamber above the expansion head spherical surface that allows expansion the ring therein as the shank is inserted into the ring.

With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the above cited prior art, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same invention and contain the same structural limitations, i.e., a screw/threaded shank, head, retaining ring, ad closure member.

Claims 1, 13, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/651003. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same invention and contain the same structural limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 13, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/980534. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because they are drawn to the same invention and contain the same structural limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached Form PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH *mch*


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER